

A randomised clinical trial evaluating the efficacy of physiotherapy after rotator cuff repair

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The optimal form of rehabilitation after rotator cuff repair has yet to be determined. A randomised clinical trial was undertaken to compare outcomes for two forms of rehabilitation for this condition: individualised supervised physiotherapy treatment, and a standardised unsupervised home exercise regime. Fifty-eight volunteers with all sizes of operatively repaired rotator cuff tears were allocated randomly to one of the two treatment groups. All subjects received a standardised home exercise regime. Subjects who were randomised to the physiotherapy group received additional individualised treatment. Independent, blinded assessments of range of motion, muscle force and functional outcome measures were performed pre-operatively, and at six, 12 and 24 weeks post-operation. At six, 12 and 24 weeks post-operation, comparable outcomes were demonstrated for both rehabilitation groups. By 24 weeks post-operation, most subjects demonstrated outcomes that were consistent with a favourable recovery, regardless of rehabilitation mode. On the basis of these results, outcomes for subjects allocated to individualised physiotherapy treatment after rotator cuff repair are no better than for subjects allocated to a standardised home exercise regime. [Hayes K, Ginn K, Walton J, Szomor Z and Murrell G (2004): A randomised clinical trial evaluating the efficacy of physiotherapy after rotator cuff repair. *Australian Journal of Physiotherapy* 50: 77-83]

Key words: Randomised Control Trial, Shoulder, Surgery, Rehabilitation

Introduction

To date, only two clinical trials have evaluated rehabilitation following rotator cuff repair (Lastayo 1998, Roddey 2002). In a well designed, randomised clinical trial comparing rehabilitation using either continuous passive motion or passive range of motion home exercises for 31 patients after rotator cuff repair, equally favourable long-term shoulder motion, muscle force and functional outcomes were demonstrated (Lastayo 1998). In the second randomised clinical trial (Roddey 2002), comparable short-term and long-term functional outcomes were demonstrated for 108 patients who rehabilitated with a standardised home exercise regime that was conveyed via either videotaped instructions or at one of four post-operative physiotherapy sessions.

Standardised shoulder rehabilitation methods that involve exercise progression according to a set post-operative time-frame fail to account for variability in characteristics that pertain to the patient, the injury, and the surgical procedure performed as treatment for a rotator cuff tear. It is plausible to assume that any of these characteristics, in particular, the size and location of the tear, presence of co-existing shoulder pathology, and surgical technique employed, may influence the rate and extent of recovery and thus rehabilitation requirements after rotator cuff repair.

An alternative to standardised post-operative rehabilitation is treatment based on an individual assessment of pain and shoulder mechanics. Individualised physiotherapy treatment after rotator cuff repair offers the possibility of tailored exercise prescription, exercise supervision and correction, patient motivation and the early identification of potential rehabilitation problems. The aim of this investigation was to

compare short-term and long-term range of motion, muscle force, and functional outcomes for subjects who rehabilitate via individualised supervised physiotherapy treatment versus a standardised unsupervised home exercise regime after rotator cuff repair.

Method

Subjects Fifty-eight subjects who underwent rotator cuff repair at the Sports Medicine and Shoulder Service, St George Hospital Campus, Sydney, between February 1999 and March 2001, volunteered to participate in this study. Included were 40 males and 18 females (mean age 60 ± 11 years, range = 41 to 83 years). Subjects who had an irreparable rotator cuff tear, an incomplete repair of a rotator cuff tear, a history of previous shoulder surgery to the involved extremity, an additional procedure at the time of surgery (e.g. glenohumeral stabilisation, capsular release), humeral, clavicular or scapular fracture, or the co-morbidity features of diabetes or rheumatoid arthritis were excluded from this study. Ethical approval for this study was granted by the South Eastern Sydney Area Health Service Ethics Committee and the University of Sydney Human Ethics Committee. Power calculations performed after 18 months of data collection determined that a minimum sample size of 57 subjects was required to have an 80% chance ($\alpha = 0.05$, $\beta = 0.2$) of detecting a difference in passive abduction range of motion of 20 degrees, if such an effect existed.

Outcome measures Outcome measures utilised in this study were:

1. Visual estimation of passive range of motion (measured in degrees) for the movements of flexion, abduction and

external rotation. These measures have demonstrated acceptable reliability, with inter-rater intra-class correlation coefficients (ICC) ranging from 0.57 to 0.70, and intra-rater ICC ranging from 0.59 to 0.67 (Hayes et al 2001).

2. Manual muscle tests, graded from 1 (trace or absent muscle contraction) to 5 (normal muscle force), for the movements of internal rotation, external rotation and elevation. These measures have demonstrated acceptable reliability, with inter-rater ICC ranging from 0.55 to 0.73, and intra-rater ICC ranging from 0.79 to 1.00 (Hayes et al 2002).

In total, eight trained assessors participated in the present investigation. Independent, blinded assessment was performed pre-operatively, and at six, 12, and 24 weeks post-operation for all range of motion and muscle force measures.

The Shoulder Service Questionnaire, a modified version of the Shoulder Rating Questionnaire (L'Insalata et al 1998), was also included for the assessment of physical symptoms, activity capacity, including items associated with sport, work and lifestyle, and overall shoulder status. The Shoulder Service Questionnaire was completed independently by each subject pre-operatively, and at six, 12, and 24 weeks post-operation.

Procedures All operations were performed as day cases, by the same surgeon, to ensure a standardised operative technique. The procedure was performed in the beach-chair position, with an interscalene block regional anaesthesia as previously described (Cummins et al 2003). Following arthroscopic examination, an open deltoid splitting approach was made into the subacromial space. Following an acromioplasty, a combination of side to side sutures and suture anchors (Mitek RC) were used for tendon to tendon and tendon to bone repair (Cummins et al 2003).

For the first post-operative day, the affected extremity was immobilised in a sling. Thereafter, all subjects were encouraged to discard the sling and commence light functional activities. During the first post-operative week, all subjects were encouraged to utilise cryotherapy^(a) and exercise three times per day in accordance with phase one of a three-phase (six month) standardised home exercise regime. Phase one exercises were issued by one of the researchers at the time of a pre-operative physiotherapy consultation. Phase one exercises consisted of ten repetitions each for elbow flexion and extension, grip formation, scapular retraction and pendular shoulder movements. Phase two exercises were issued by the treating surgeon at the time of the first post-operative clinic, eight days post-operation. Phase two exercises consisted of ten repetitions each for active-assisted shoulder flexion and external rotation (one to two daily sessions); and ten repetitions, five seconds duration each for isometric shoulder flexion, extension, abduction, adduction, external rotation and internal rotation (three to five daily sessions). Phase three exercises were issued by the treating surgeon at the time of the second post-operative clinic, six weeks post-operation. Phase three exercises consisted of five repetitions, ten seconds duration each for flexion, horizontal flexion and external rotation (one daily session); ten repetitions each for active-assisted shoulder flexion, extension, external rotation and hand behind back (one to two daily sessions); three sets of ten repetitions each for theraband-resistive retraction, flexion, abduction,

adduction, external rotation and internal rotation (two daily sessions).

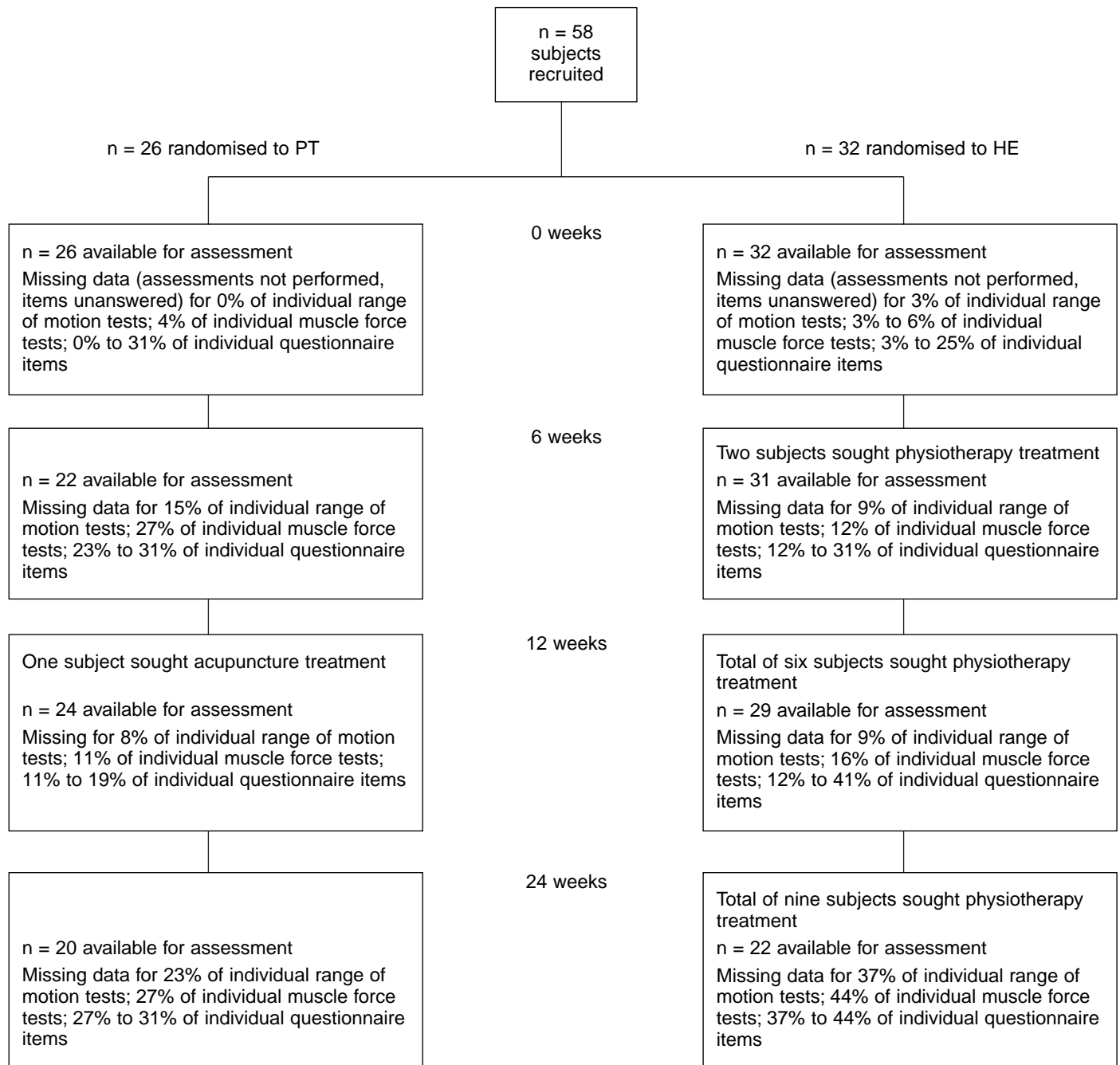
Recruitment to the trial took place during the first post-operative clinic. Allocation to either the individualised physiotherapy group or standardised home exercise group was predetermined by a random numerical sequence of computer generated digits. While the investigator was aware of a potential subject's intended form of allocation, participants were unaware of the same at the time they consented to the trial. Baseline assessment of passive range of motion and muscle force, and completion of the Shoulder Service Questionnaire had previously been undertaken at the time of the pre-operative surgical consultation.

The participating surgeon encouraged all subjects to comply with their allocated form of rehabilitation. With the exception of this encouragement, routine post-operative follow-up by the participating surgeon, and the previously described three-phase home exercise regime, subjects in the standardised home exercise group received no other rehabilitation. Subjects in the physiotherapy group received individualised physiotherapy treatment in addition to the standardised home exercise regime. In total, seven physiotherapy clinics agreed to participate in this trial.

Individualised physiotherapy treatment was commenced during the second post-operative week. All aspects of physiotherapy management, including treatment content, rate of rehabilitation progression, and total number of sessions were determined by the treating physiotherapist. Where deemed appropriate, the standardised home exercise regime that had been issued by the treating surgeon was modified with respect to content and frequency of exercise. Accordingly, individualised physiotherapy treatment and the adjuvant home exercise regime may have consisted of any combination of exercises, manual therapy techniques, physical modalities of ice and moist heat, and rehabilitation and home exercise advice. Treating physiotherapists were advised not to advocate exercises or functional activities that caused an increase in pain above resting intensity. Subjects in the individualised physiotherapy group were encouraged to attend scheduled appointments and fulfil prescribed home exercise obligations. On average, subjects in the individualised physiotherapy group received 16 ± 11 treatments over 17 ± 9 weeks. No formal attempt was made to monitor compliance with the standardised or physiotherapist-determined home exercise routine.

Subjects who sought treatment in addition to their allocated form of rehabilitation were regarded as allocated treatment non-compliers. Data from these subjects, both before and after the point of treatment non-compliance, were analysed in the group to which they had initially been assigned.

Data analysis Mean and median (95% confidence interval) outcomes for the individualised physiotherapy group and standardised home exercise group, and between-group (95% confidence interval) difference scores were calculated for each assessment occasion. Range of motion and functional outcome data collected for the individualised physiotherapy group and standardised home exercise group for the period that encompassed pre-operation to 24 weeks post-operation were analysed with a factorial (group x time) ANOVA with four repeated measures on the time factor. Muscle force data collected for these two groups for the same assessment period were analysed with Friedman tests and Mann Whitney U tests.



PT = individualised physiotherapy group, HE = standardised home exercise group

Figure 1. Trial flow diagram

Descriptive and clinical characteristics for allocated treatment non-compliers and the remaining cohort were analysed with Student's t-tests and Fisher exact tests. Mean (95% confidence interval) and median outcome for allocated treatment non-compliers were calculated for the first assessment occasion that preceded the commencement of an additional form of rehabilitation.

All analyses reported in this study were performed with SPSS v 10.0 statistical software. For all analyses, $p < 0.05$ was selected as the level of statistical significance.

Results

Key descriptive and clinical characteristics for subjects in the individualised physiotherapy group and standardised home exercise group at the commencement of the study are displayed in Table 1. Pre-operative measures for the individualised physiotherapy group and standardised home exercise group are presented in Tables 2–4. The proportion of missing data for both treatment groups, for each of the individual pre-operative measures is presented in Figure 1. With the exception of elevation muscle force, which was

Table 1. Characteristics of subjects in the individualised physiotherapy group and standardised home exercise group. Data are means \pm SD (range).

	Physiotherapy group (<i>n</i> = 26)	Home exercise group (<i>n</i> = 32)
Mean age (years)	58 \pm 10 (41–81)	62 \pm 11 (42–83)
Mean tear size (cm ²)	5 \pm 7 (1–27)	6 \pm 8 (1–30)
Mean pre-operative duration of symptoms (months)	12 \pm 16 (0–48)	19 \pm 27 (1–96)
Gender (M:F)	20:6	20:12
Dominance (dominant: non-dominant: ambidextrous)	20:5:1	19:13:0
Mechanism of onset (trauma: insidious)	19:7	14:18
Torn tendons†	SS = 18 SS + IS = 1 SS + SSC = 5 SS + IS + SSC = 2	SS = 20 SS + IS = 1 SS + SSC = 6 SS + IS + SSC = 5
Tear type (full thickness: partial thickness)	22:4	28:4
Workers compensation cases	4	6

†SS = supraspinatus, IS = infraspinatus, SSC = subscapularis.

statistically greater for the physiotherapy group (mean between-group difference = 0.5 (0 to 0.5, $p < 0.03$), there were no significant differences between the two groups prior to operation for any of the characteristics or pre-operative measures listed in Tables 1–4.

Post-operative outcomes for the individualised physiotherapy group and standardised home exercise group are displayed in Tables 2–4. The proportion of missing data for both groups, for each of the individual post-operative measures, is presented in Figure 1. There were no statistically significant differences between the two groups post-operatively for any passive range of motion, muscle force or functional outcome measure.

Throughout the course of this investigation, one subject from the individualised physiotherapy group sought acupuncture treatment and nine subjects from the standardised home exercise group sought individualised physiotherapy treatment (Figure 1). These ten subjects, who did not comply with their allocated form of rehabilitation, were compared to the remaining total cohort for each of the key descriptive and clinical characteristics listed in Table 1. The only characteristic which was statistically different for the two groups was mean age, with allocated treatment non-compliers being significantly older than those subjects who complied with their allocated treatment (mean age: allocated treatment non-compliers = 67 \pm 11 years, total cohort minus allocated treatment non-compliers = 59 \pm 10 years, $p = 0.03$).

Discussion

In this study, similar passive range of motion, muscle force, and functional outcomes were demonstrated at six, 12 and 24 weeks post-operation for subjects who were allocated to rehabilitation via one of two distinct treatment methods: individualised physiotherapy treatment, or a standardised home exercise regime. By 24 weeks post-operation, both groups demonstrated outcomes that were consistent with near full passive shoulder range of motion and muscle force capacity, and a markedly improved overall shoulder status. In a previous study involving 108 cases of rotator cuff repair

(Roddey 2002), comparable self-reported outcomes for shoulder pain, function, and treatment satisfaction were demonstrated at 12, 24, and 52 weeks post-operation for subjects who rehabilitated according to a standardised home exercise regime that was conveyed via one of two distinct instructional methods: physiotherapist-instruction or videotaped-instruction. On the basis of these collective results, the involvement of a physiotherapist would appear to offer no additional benefit to that associated with a standardised unsupervised home exercise regime in the process of rehabilitation after rotator cuff repair. From a financial perspective, the relative costs associated with the delivery of individualised physiotherapy treatment and standardised home exercise render the former the more costly of the two rehabilitation methods after rotator cuff repair.

In this study, a sub-group of 10 subjects, who were significantly older than the remaining cohort, sought treatment in addition to their allocated form of rehabilitation. Nine of these 10 treatment non-compliers were initially allocated to the standardised home exercise group and elected to seek physiotherapy treatment. The remaining treatment non-complier was initially allocated to the individualised physiotherapy group and elected to seek acupuncture treatment. Post-operative assessment results, therefore, represented the outcome associated with referral to one particular method of rehabilitation relative to another, including additional rehabilitation decisions made by subjects in a clinical setting in an attempt to satisfy their specific recovery needs.

The decision to seek an alternative treatment would seem to imply dissatisfaction with the allocated form of rehabilitation and, in this study, to imply substantially greater dissatisfaction with the standardised home exercise regime. While reasons for seeking an alternative treatment are unknown, a sub-optimal rate of post-operative recovery for this subgroup of subjects may have contributed to allocated treatment non-compliance.

For the six-month duration of this investigation, missing data accounted for between 0% and 31% of assessment results for the individualised physiotherapy group, and between 3% and

Table 2. Range of motion outcomes for the individualised physiotherapy group and standardised home exercise group

		0 weeks mean (95% CI)	6 weeks mean (95% CI)	12 weeks mean (95% CI)	24 weeks mean (95% CI)
Flexion	PT	148 (139 to 157)° n = 26	130 (118 to 142)° n = 22	141 (129 to 153)° n = 24	150 (142 to 158)° n = 20
	HE	134 (122 to 146)° n = 31	111 (99 to 123)° n = 31	136 (125 to 147)° n = 29	144 (132 to 156)° n = 20
	<i>Between-group difference</i>	14 (-2 to 30)°	19 (1 to 37)°	5 (-11 to 21)°	6 (-8 to 20)°
Abduction	PT	133 (122 to 144)° n = 26	108 (93 to 123)° n = 22	125 (110 to 140)° n = 24	142 (130 to 154)° n = 20
	HE	120 (108 to 132)° n = 31	95 (85 to 105)° n = 31	119 (106 to 132)° n = 29	130 (117 to 143)° n = 20
	<i>Between-group difference</i>	13 (-3 to 29)°	13 (-3 to 29)°	6 (-12 to 24)°	12 (-6 to 30)°
External rotation	PT	55 (49 to 61)° n = 26	34 (26 to 42)° n = 22	42 (34 to 50)° n = 24	51 (46 to 56)° n = 20
	HE	47 (40 to 54)° n = 31	31 (26 to 36)° n = 31	41 (34 to 48)° n = 29	43 (36 to 50)° n = 20
	<i>Between-group difference</i>	8 (0 to 16)°	3 (-5 to 11)°	1 (-9 to 11)°	8 (0 to 16)°

PT = individualised physiotherapy group, HE = standardised home exercise group, n = number of subjects assessed

Table 3. Muscle force outcomes (manual muscle test grades) for the individualised physiotherapy group and standardised home exercise group

		0 weeks median (95% CI)	6 weeks median (95% CI)	12 weeks median (95% CI)	24 weeks median (95% CI)
Internal rotation	PT	5 (5 to 5) n = 25	5 (5 to 5) n = 19	5 (5 to 5) n = 23	5 (5 to 5) n = 19
	HE	5 (5 to 5) n = 31	5 (5 to 5) n = 29	5 (5 to 5) n = 27	5 (5 to 5) n = 18
	<i>Between-group difference</i>	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
External rotation	PT	5 (4.5 to 5) n = 25	5 (4.5 to 5) n = 19	5 (5 to 5) n = 23	5 (5 to 5) n = 19
	HE	5 (4.5 to 5) n = 31	5 (4.5 to 5) n = 29	5 (4.5 to 5) n = 27	5 (5 to 5) n = 18
	<i>Between-group difference</i>	0 (0 to 0.5)	0 (-0.5 to 0.5)	0 (0 to 0.5)	0 (0 to 0)
Elevation	PT	4.5 (4.5 to 5) n = 25	4.5 (4 to 5) n = 19	5 (4.5 to 5) n = 23	5 (4.5 to 5) n = 19
	HE	4.5 (4 to 4.5) n = 30	4.5 (4 to 4.5) n = 29	4.5 (4 to 5) n = 27	5 (4.5 to 5) n = 18
	<i>Between-group difference</i>	0.5 (0 to 0.5)	0 (-0.5 to 0.5)	0 (0 to 0.5)	0 (0 to 0)

PT = individualised physiotherapy group, HE = standardised home exercise group, n = number of subjects assessed

44% of assessment results for the standardised home exercise group. As a consequence of missing data, the likelihood of finding statistically significant between-group outcome differences for the given effect size and level of statistical significance was reduced. In a previously reported study (Roddey 2002) comparing the efficacy of two instructional approaches to home exercise after rotator cuff repair, similar levels of missing data were reported, with 38% of assessment results missing throughout the 12 month duration of the trial. The results of this and the present investigation highlight the inherent difficulty associated with the process of data collection in post-operative clinical research.

Although demonstrating marked improvement in overall shoulder status by the end of the present study, subjects in the

individualised physiotherapy group and standardised home exercise group reported mean residual functional deficits of 14% and 32% respectively at 24 weeks post-operation. Residual functional deficits following rotator cuff repair and subsequent rehabilitation have previously been reported at 52 weeks post-operation (Roddey 2002). In the absence of data beyond 52 weeks post-operation, it remains to be determined whether rotator cuff repair and post-operative rehabilitation ultimately results in a full resolution of physical symptoms and a full restoration of functional capacity for work, sport and lifestyle pursuits.

For the short-term following rotator cuff repair, both the individualised physiotherapy group and standardised home exercise group demonstrated a decrease in all passive

Table 4. Functional outcomes for the individualised physiotherapy group and standardised home exercise group

		0 weeks mean (95% CI)	6 weeks mean (95% CI)	12 weeks mean (95% CI)	24 weeks mean (95% CI)
Physical symptoms	PT	55 (48 to 62)% n = 26	41 (34 to 48)% n = 20	31 (23 to 39)% n = 23	19 (14 to 24)% n = 19
	HE	61 (55 to 67)% n = 31	43 (35 to 51)% n = 30	35 (26 to 44)% n = 28	34 (23 to 45)% n = 20
	<i>Between-group difference</i>	-6 (-14 to 2)%	-2 (-12 to 8)%	-4 (-16 to 8)%	-15 (-27 to -3)%
Sport	PT	47 (34 to 60)% n = 18	49 (38 to 60)% n = 18	28 (19 to 37)% n = 21	18 (10 to 26)% n = 18
	HE	45 (33 to 57)% n = 24	48 (37 to 59)% n = 24	31 (20 to 42)% n = 19	30 (17 to 43)% n = 18
	<i>Between-group difference</i>	2 (-16 to 20)%	1 (-15 to 17)%	-3 (-17 to 11)%	-12 (-26 to 2)%
Work	PT	68 (57 to 79)% n = 25	59 (49 to 69)% n = 19	47 (38 to 56)% n = 23	36 (24 to 48)% n = 18
	HE	65 (58 to 72)% n = 29	60 (49 to 71)% n = 30	48 (38 to 58)% n = 26	43 (30 to 56)% n = 19
	<i>Between-group difference</i>	3 (-9 to 15)%	-1 (-15 to 13)%	-1 (-13 to 11)%	-7 (-25 to 11)%
Lifestyle	PT	59 (50 to 68)% n = 25	55 (44 to 66)% n = 20	39 (31 to 47)% n = 23	22 (13 to 31)% n = 19
	HE	69 (62 to 76)% n = 30	56 (45 to 67)% n = 30	41 (30 to 52)% n = 28	45 (32 to 58)% n = 20
	<i>Between-group difference</i>	-10 (-22 to 2)%	-1 (-17 to 15)%	-2 (-14 to 10)%	-23 (-39 to -7)%
Overall shoulder status	PT	65 (57 to 73)% n = 25	35 (27 to 43) n = 19	24 (15 to 33)% n = 23	14 (7 to 21)% n = 19
	HE	75 (67 to 83)% n = 28	35 (28 to 42)% n = 30	30 (20 to 40)% n = 27	32 (21 to 43)% n = 20
	<i>Between-group difference</i>	-10 (-22 to 2)%	0 (-10 to 10)%	-6 (-20 to 8)%	-18 (-30 to -6)%

Outcomes for the various categories of the Shoulder Service Questionnaire are represented as percentage values. The maximum attainable value was 100%. For each category, a higher score denotes greater disability. For between-group difference, a negative value denotes greater disability for the standardised home exercise group.

shoulder range of motion and elevation muscle force measures. In contrast, for the same post-operative period, both groups reported improvements in physical symptoms, activity capacity (work), and overall shoulder status. It would appear from these results that symptom relief was a more important determinant of self-assessed functional recovery in the short term than passive range of motion and isometric muscle force status. In the absence of corresponding data for this population of patients, it remains to be determined whether active shoulder range of motion assessments better reflect self-assessed functional recovery following rotator cuff repair.

Previous studies investigating the reliability of muscle force assessments have shown that manual muscle tests lack the sensitivity to discern between various outcomes in grade 4 to 5 test categories (Beasley 1956, Hayes et al 2002). In the present study, most muscle force outcomes were recorded in grade 4 to 5 test categories. It could be argued that a more discriminative method for muscle force assessment, such as that afforded by hand-held dynamometry (Hayes et al 2002), may have provided the means for discerning subtle between-group and time-dependent variations in muscle force outcomes, if such variations existed.

In conclusion, outcomes for subjects allocated to individualised physiotherapy treatment after rotator cuff repair were comparable to those for subjects allocated to a standardised home exercise regime. In the longer-term, most subjects demonstrated marked improvements in passive shoulder range of motion, muscle force, and functional capacity, irrespective of post-operative rehabilitation method. A substantial proportion of subjects who were allocated to rehabilitation via a standardised home exercise regime sought physiotherapy treatment, implying a preference for greater rehabilitation assistance in some subjects following rotator cuff repair.

Footnote ^(a)Cryo/Cuff Aircast – model, Summit NJ

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